

EXHIBIT B

Parke-Davis

RECORD OF FDA CONTACT

Date: October 6, 1993 Signature Name: Janeth L. Turner

Product Identification: Gabapentin
(Add CI No. if known) CI-945

NDA No: 20-235 IND No: 28,454
Initiated by: ☒ P-D ☐ FDA Made: ☐ In Person ☒ Phone

FDA Contact Person:

Name: Nancy Chamberlain Title: CSO
Division: Neuropharmacology Phone No. 1-301-443-3830

Purpose of Contact (Subject):

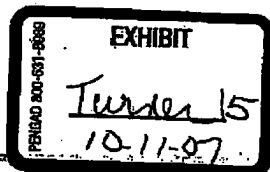
Status of FDA review

Summary:

Dr. Katz and Dr. Leber have decided to send the approvable package to Dr. Temple prior to negotiating labeling with us. The original version of the felbamate labeling had needed extensive revision, and attempting to work with the company to revise it prior to sending it to Dr. Temple had resulted in much confusion. They felt that the most recent revisions which we had submitted on September 3 were very good and developing an FDA version based on this, sending it to Dr. Temple as part of the approvable package, and then sending it to us to begin negotiations would be the most expeditious method.

They have not yet sent the approvable package to Dr. Temple. There is nothing which FDA needs from us prior to sending the letter. The delay appears to be fine-tuning the labeling. They are reviewing every word, and since it has been so long since the Advisory Committee Meeting, sometimes they need to go back and refresh their memory as to what occurred.

Nancy must have Dr. Katz' permission to tell me when it is sent to Dr. Temple. Nancy will follow up with Dr. Katz to determine if she can so inform me. Unless we instruct FDA otherwise, the approvable letter will be addressed to me. Nancy will call me when it is signed and send me a FAX of the letter once it is date stamped.



Confidential

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While there is nothing which FDA needs from us prior to sending the approvable letter, Nancy stated that the request for additional information in the Environmental Assessment, which had been relayed to Al Brankiewicz earlier today, should be responded to as soon as possible. While this should not delay the approvable letter, sometimes it helps to move things along at FDA to know that none of this sort of thing is outstanding.

Abstract:

Package Insert negotiations will begin when we receive the approvable letter. The approvable package has not yet been sent to Dr. Temple.

Action:

None

PC:

W. Merino	I. Martin
S. Brennan	A. Brankiewicz
CBI, AA	B. McManus (distribution)
RA, AA: CI-945 File, NDA 20-235	